

## **CLIA QUALITY ASSURANCE TRAINING AID**

This document has been prepared as a self test to aid laboratories in developing or improving their quality assurance activities. The questions are designed to cover all aspects of compliance with CLIA regulations (preanalytic, analytic, and post analytic). Each item should be adapted to your specific operation. Every item may not be applicable to your laboratory. It is our hope this document will help you plan and evaluate the overall quality of the lab tests performed at your facility. Addressing all the items in this questionnaire will not guarantee a flawless inspection by your certification agency, but should certainly help you be prepared for any inspection process. Any accrediting agency (CAP, COLA, JCAHO, etc) can have stricter requirements than these.

### **PERSONNEL**

1. Do you have documentation (copy of a certificate, diploma, etc) of the highest educational degree obtained by each person performing lab tests in your facility?
2. Do you have an in-date copy of the Utah License to Practice Medicine for your clinical consultant?
3. Do you have documentation of the education and experience required for your director to qualify as a CLIA director for the type of lab tests you perform in your facility?
4. Do you have documentation of the education and experience required for any technical consultant you have who is not included in #1, #2, or #3 above?
5. Do you have a process to train new employees for lab testing? (Even if new employees are clinical lab scientists with many years experience, they need to be trained in your testing methods, reporting system, specimen labeling, paper work, etc.) Do you document this training?
6. Who does the annual lab testing competency checks for testing personnel? Do you have documentation of these checks? Has it been more than one year since the last check?
7. Is there a 6 month competency check for new employees (you can use your training form)?
8. Is there documentation of training for all applicable testing personnel on any new test, instrument, or change of manufacturer for a kit test you perform? Even a change in computer software for an instrument may need to be given to employees as an inservice.
9. Can all testing personnel perform all tests in your facility? If not, do you have a list of who (name or title) can perform which tests (or who cannot perform which tests) signed by the CLIA director? This list is called a test authorization list.
10. Does the director delegate any of his/her duties, such as writing the procedures, to someone else? If

yes, has the director signed a list of such duties and who they are delegated to? NOTE: these duties may only be delegated to a person who qualifies as a technical consultant or supervisor. (Director's duties are listed in Appendix A.)

## **PATIENT TEST MANAGEMENT**

1. Are there written instructions for collecting patient specimens, for labeling specimens, for processing patient specimens?
2. How does the labeling process assure the test is reported on the correct patient if there are two people with the same name?
3. How can you tell which sample belongs to which test report if there are multiple samples on the same patient the same day (ie glucose tolerance test, or redraw due to specimen problem)?
4. Is there a specimen rejection policy? Is there documentation when a specimen is rejected?
5. If there is more than one testing person in your facility, does the record system show who performed each test (initials or number code)?
6. Can you follow the process for each different test from the clinicians order to the final report?
7. Do you occasionally check a few patient results to assure they are complete and accurate?
8. Do you have any panic values for the tests you perform (values so low or so high that the patient must have immediate attention)? If yes, do all testing personnel know what these values are and what to do if they get a panic result on a test?
9. If a test reporting error is discovered, do you issue a corrected report? Is the problem documented? Do you keep a copy of both reports? Can the clinician tell which report is correct?
10. Do you keep all test records for 2 years (test requests, worksheets, log books, quality control records, test reports)? Immunohematology (blood bank) records must be kept 5 years, pathology reports must be kept 10 years. NOTE: Medicare and Medicaid can ask for physician requests for tests they reimbursed back 5 years.
11. If you receive specimens from an outside source for testing (home health, nursing home, etc), do they have written instructions from you on how to collect, label, and transport the specimens? Do you document when these instructions are not followed?

## QUALITY CONTROL

1. Can you show you have the proper environmental conditions for the tests you perform? (i.e., refrigerator temperature charts for reagents that require 2-8 degrees C storage; room temperature charts for the QBC which should not be used if the room temperature is below 68 degrees, etc)?
2. Do you have written instructions for each test you perform (procedures)? You may use manufacturer's instructions; but usually you have to add lab specific information such as how often you do controls, where you record the control results, when do you use external versus internal controls, what do you do if the test system fails (invalid results, out of reagents, etc).
3. Have any changes to manufacturer's instructions been validated, written into the procedure, and approved (dated and signed) by the CLIA director?
4. Do you have documentation that each new instrument, test system, kit (change from one manufacturer to another) meet the manufacturer's performance specifications? This is commonly called method validation. For example, if the chemistry instrument's range for glucose is stated by the manufacturer to be 50 to 500, and if you will accept the instrument's readings of 50 to 500, have you proven your instrument will be accurate at both the 50 and the 500? You do this validation when you begin to use the test system. Most manufacturers will provide materials for you to check their instrument's reportable range if you make it part of the purchase contract. As well as accuracy, you may need to check precision (you get the same result when you repeat the same specimen on the same day and on different days), decision level (will a positive on the previous kit still be positive on this new kit).
5. Do you follow manufacturer's instructions for instrument maintenance and document it?
6. Do you check the instrument's calibration according to manufacturer's instructions, at the frequency recommended by the manufacturer or at least every 6 months as required by CLIA? Do you have documentation of this calibration or calibration verification (including instrument printouts if the machine provides them)?
7. Is there documentation of at least 2 levels of control (positive and negative for qualitative tests) for each test you do - each day you do the test? A few tests have more or less stringent requirements (culture susceptibility testing may be performed weekly under certain circumstances; gram stain control is each new batch or lot number; etc).
8. Are controls tested the same way and the same time as patient specimens?
9. If the controls fail their acceptable range, are all patient tests repeated in a run for which the controls pass? If the lab cannot get the controls within range, is there a contingency plan (send the test to a reference lab, preserve the specimen until the instrument is repaired, etc)? Is there documentation the contingency plan was followed?

10. Are all test systems, control materials, reagents, within the expiration date supplied by the manufacturer? CLIA does not allow testing patient specimens with expired reagents.

11. If a reagent has a revised expiration date after opening (ie. Coulter Clenz solution, QBC collection tubes, etc); reconstitution (coagulation reagents); or upon storing at room temperature rather than refrigerator temperature (ie certain rapid strep reagents); does the lab put the open date, reconstitution date, or removal date on the reagent so that all personnel can tell when the revised expiration date is reached?

### PROFICIENCY TESTING

1. Are you enrolled in proficiency testing from a HCFA approved agency (appendix B) for every subspecialty or regulated analyte (appendix C) as required by CLIA (**proficiency testing is encouraged, but not required for waived testing methods**)?

2. Are proficiency testing samples treated the same as patient specimens? Tested the same number of times? Tested with the same method? Tested by personnel who test patients (not always tested by the supervisor)? Tested in a run with patient specimens if at all possible?

3. When you receive a report of an unacceptable result, do you investigate the error? Do you document your investigation?

4. When you find a problem with proficiency testing, do you check patient testing done during that time to see if patient results were also affected?

5. Do you keep all proficiency testing records at least 2 years (report forms submitted to the company, instrument printouts, worksheets, attestation statement signed by testing personnel and director, the evaluation report, and any actions taken when the results were unacceptable)?

### QUALITY ASSURANCE

1. Do you have a written quality assurance plan to ensure accurate patient testing by incorporating evaluations of employee training and competency; patient test management; quality control and proficiency test review?

2. Do you have a mechanism to compare the relationship of test results to patient information that is inconsistent (a pregnancy test report for Steven Smith; a potassium result of 7.3; a hemoglobin of 13.2 with a hematocrit of 18)?

3. For any test you do for which you do not have proficiency testing (not required or not available),

what mechanism do you have to check the quality of that testing every 6 months?

4. If you have two methods for the same test and do proficiency testing on the primary method, what is the mechanism to check the accuracy of the secondary method at least once a year?

5. Do you investigate lab testing problems to determine if personnel need additional training?

6. Is there documentation of quality assurance audits or activities performed in your lab?

7. Do you have a system for investigating complaints to determine the cause? Do you document the remedy taken? Do you check later to make certain the remedy solved the problem?

8. Do you review quality assurance results with all your staff?

9. Do you maintain all quality assurance records for at least 2 years?

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### APPENDIX A

#### **493.1407 Standard; Laboratory director responsibilities.**

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

- (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively.
- (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.
- (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.
- (d) Each individual may direct no more than five laboratories.
- (e) The laboratory director must--
  - (1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
  - (2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;
  - (3) Ensure that--
    - (I) The test methodologies selected have the capability of providing the quality of results required for patient care;
    - (ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
    - (iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;
  - (4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--
    - (I) The proficiency testing samples are tested as required under Subpart H of this part;
    - (ii) The results are returned within the time frames established by the proficiency testing program;
    - (iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and
    - (iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;
  - (5) Ensure that the quality control and quality assurance programs are established and maintained to

assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(12) Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(13) Ensure that an approved procedure manuals available to all personnel responsible for any aspect of the testing process; and

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

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APPENDIX B**

ACCUTEST	(800) 356-6788
AMERICAN ACADEMY of FAMILY PHYSICIANS (AAFP)	(800) 274-2237
AMERICAN ASSOCIATION of BIOANALYSTS (AAB)	(800) 234-5315
AMERICAN PROFICIENCY INSTITUTE (API)	(800) 333-0958
AMERICAN SOCIETY of INTERNAL MEDICINE - MEDICAL LABORATORY EVALUATION (ASIM-MLE)	(800) 338-2746
COLLEGE of AMERICAN PATHOLOGISTS (CAP) / EXCELL	(800) 323-4040
OHIO DEPARTMENT of HEALTH	(614) 644-2278
WISCONSIN STATE LABORATORY of HYGIENE	(800) 462-5261



## CLIA QA TRAINING AID

### APPENDIX C

Tests Requiring Proficiency Testing (not for waived methods)

#### SUBSPECIALTIES:

BACTERIOLOGY - includes antigen detection kits (rapid strep, chlamydia, group B strep); cultures; gram stains

MYCOBACTERIOLOGY - cultures, stains

MYCOLOGY - cultures (**not DTM for presence or absence**)

PARASITOLOGY - direct preps, concentrated preps, stains, antigen detection

#### ANALYTES WITHIN THE SPECIALTIES/SUBSPECIALTIES

SYPHILIS SEROLOGY - all tests

##### GENERAL IMMUNOLOGY -

Alpha-1 antitrypsin	IgA
Alpha-fetoprotein (tumor marker)	IgG
Antinuclear antibody	IgE
Antistreptolysin O	IgM
Anti-human immunodeficiency virus (HIV)	Infectious mononucleosis
Complement C3	Rheumatoid factor
Complement C4	Rubella
Hepatitis markers (HBsAg, anti-HBc, HBeAg)	

##### ROUTINE CHEMISTRY -

Alanine aminotransferase (ALT/SGPT)	Creatine
Albumin	Glucose
Alkaline phosphatase	Iron, total
Amylase	Lactate dehydrogenase (LDH)
Aspartate aminotransferase (AST/SGOT)	LDH isoenzymes
Bilirubin, total	Magnesium
Blood gas (pH, pO <sub>2</sub> , and pCO <sub>2</sub> )	Potassium
Calcium, total	Sodium
Chloride	Total Protein
Cholesterol, total	Triglycerides
Cholesterol, high density lipoprotein	Urea Nitrogen
Creatine kinase	Uric Acid
Creatine kinase, isoenzymes	

## ENDOCRINOLOGY

Cortisol  
Free Thyroxine  
Human Chorionic Gonadotropin (HCG)  
T<sub>3</sub> Uptake

Triiodothyronine  
Thyroid-stimulating hormone  
Thyroxine

## TOXICOLOGY

Alcohol (blood)  
Blood lead  
Carbamazepine  
Digoxin  
Ethosuximide  
Gentamicin  
Lithium  
Phenobarbital

Phenytoin  
Primidone  
Procainamide (and metabolite)  
Quinidine  
Theophylline  
Tobramycin  
Valproic Acid

## HEMATOLOGY

Cell identification or WBC differential  
Erythrocyte count (RBC)  
Hematocrit  
Hemoglobin  
Leukocyte count (WBC)

Platelet count  
Fibrinogen  
Partial thromboplastin time  
Prothrombin time

## IMMUNOHEMATOLOGY

ABO Group & Rh Type  
Antibody Detection  
Antibody Identification  
Compatibility Testing

CYTOLOGY - pap smear (when available)